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REVIEW-THEMED ISSUE

Understanding the UK Psychoactive Substances Act

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This review paper is based on a talk given at the British Pharmaceutical Society Winter Meeting in 2018 derived from the Home Office Report on the workings of the UK Psychoactive Substances Act (PSA) published in November 2018. The review deals with the context in which the PSA 2016 arose and how this piece of legislation differs from other UK drug regulations. It attempts to put the PSA in context with other control schemes being instituted around the world and to assess the success of the Act in its first 2 years of implementation. For more details the reader is referred to Review of the Psychoactive Substances Act 2016, Home Office, November 2018.

KEYWORDS
drug legislation, novel psychoactive substances

1 | INTRODUCTION

The idea of classifying drugs to represent a hierarchy of risk arose in the 1931 UN Convention for Limiting the Manufacture and Regulating the Distribution of Narcotic Drugs.[1] (It is interesting to note that this approach has been revisited recently in an attempt to devise a more objective approach to classifying drug harms.[2,3]) An Expert Committee on Drug Dependence was established in 1968 to recommend to the World Health Organization, which substances should be subject to the Convention.[4] The Convention is imperfect and subject to ambiguity; however, it would be difficult to change the current systems without rewriting or cancelling the existing documentation.[4] National systems of control such as the UK Misuse of Drugs Act (1971) were designed to be compliant with the UN Conventions.

The world is changing and many of the drugs now being used recreationally are novel psychoactive substances (NPS), which are newly introduced chemicals that mimic or improve on the properties of a drug already subject to legal controls.[1,5,6] Suppliers of these drugs wish to run a legal business; therefore, as soon as risks are identified and banning orders are put in place, they discontinue selling their first choice chemical and substitute an alternate structure that is not covered by the ban. This process could go on indefinitely as there are virtually infinite numbers of chemical structures to choose from. A search of internet sites reveals that several hundred different chemicals are available at any given time. These are sometimes supplied as single substances or as mixtures often with herbal material and are sold by so-called *head shops* or through the internet. Internet commerce has allowed NPS to be introduced to human use very rapidly and often multiple deaths occur in the user group before risks are identified.

Ireland and New Zealand (NZ) were amongst the first countries to put legislation in place in an attempt to deal with NPS. The recognition that Irish youth had the highest use of NPS in Europe[7,8] mainly sourced from *head shops* led to a phased legislative approach by the Irish government. Initially over 100 substances were added to those controlled under the Misuse of Drugs Act in May 2010 and then the Criminal Justice (Psychoactive Substances) Act was enacted in August 2010.[7,8] This Act made it illegal to sell a psychoactive substance that may be used for human consumption and most of the *head shops* closed within months of the Act coming into force. The NZ Psychoactive Substances Act 2013 took a different approach[9] and set up a legal framework for the testing, manufacture, sale and regulation of psychoactive products. Selected NPS were intended to be sold through licensed outlets after undergoing rigorous clinical testing to ensure they were safe for human consumption before sale was permitted. The Act acknowledges the demand for psychoactive substances and focuses on ensuring that this need is met in a low-risk manner. The regulations were not permissive and any substance not licensed was presumed to be banned. This new Act also runs in parallel with the existing NZ Misuse of Drugs Act and only applies to new substances not covered under that Act. It tried to balance control of supply with demand reduction and problem limitation strategies.[1,4,10] However, implementation was not without problems and following the introduction of the new Act, hundreds of substances previously

legally available were reduced to a list of 41 given temporary approval by an expert committee pending demonstration of their safety. After only a few months of operation this important experiment was suspended and as of 8 May 2014 all NPS previously available in NZ were banned. Uncertainty over the safety of these products led to all interim licenses being suspended until the government had put an adequate testing regimen in place. This responded to concerns expressed in the media rather than on scientific evidence.[11,12]

The UK Psychoactive Substances Act 2016 (PSA) thus arose in a period of mixed success for legislation introduced in other countries. It was devised as a reaction to the unsatisfactory legal control of novel substances introduced to the UK recreational drugs market under the pre-existing UK legal framework.[13] Prior to 2016 it was necessary to bring any new substance under the control of the Misuse of Drugs Act (MDA) in order to make its supply and use illegal; this was both tedious and time consuming. Indeed, it was often possible to introduce an analogue of the original drug during the time taken to control the supply of the first rendering the control attempt ineffective. The Temporary Class Drug Order was introduced as a rapid way of providing legal control of a new substance for 12 months whilst its full harms were assessed preparatory to control under the MDA but this was regarded as unsatisfactory for a variety of reasons.[1]

2 | SPECIFIC FEATURES OF THE UK PSA

It was necessary to control the open sale of psychoactive substances in the UK, both in stores and online, in order to protect citizens from the risks posted by untested, unknown and potentially harmful drugs. Prior to the introduction of the PSA, *head shops* were freely selling so called *legal highs*, which often caused serious toxicity in those taking them and some deaths were recorded.

As mentioned in the introduction there was a major problem caused by new drugs, with slight differences in chemical make-up, rapidly appearing on the market in response to legislation when particular substances were banned. The lack of sustained removal of NPS from the market was due to the time-consuming nature of instituting controls under the MDA where evidence had to be collected by the Advisory Council on Misuse of Drugs (ACMD) to establish that the substance to be controlled was harmful, recommendations made as to which class and schedule of the MDA the substance should be placed in and then a Statutory Instrument had to be prepared and submitted for Parliamentary approval before the substance became legally controlled. There was a race to institute control followed by rapid evasion of these controls that seemed always to result in replacement of a banned substance with something similar in very short order.

It was necessary to reduce the number of people using psychoactive substances, including in subpopulations where prevalence was particularly high, such as young people, the homeless and those in prisons. The erroneous concept that *legal highs* were safe because they were readily available from *head shops* or via the internet was seen as a major factor in the use of such substances. On the same reasoning, it was desirable to reduce the various health and social harms associated with psychoactive substances, such as hospital admissions, deaths and violence.

Unlike controls provided by the MDA, where possession of even small amounts of Class A drugs is a serious offence potentially punishable by a prison sentence, there is no offence of possession for the user under the PSA unless the user is in in a custodial institution e.g. in prison. The sanctions of the PSA are firmly directed at those supplying the substances to the user.[1]

There is a specific exemption for any substance within the scope of the PSA that is used as a medicine. There is also a specific exemption for any substance within the scope of the PSA that is being used in basic or clinical research. There is, however, an implicit understanding that once a substance covered by the PSA is demonstrated to be harmful, it should be made subject to control under the MDA. Once this has been put in place, especially if the substance in question is made subject to Class A Schedule 1, a Home Office license would be needed in order to conduct research with it, raising the issue of significant downstream barriers to research,[14,15] although this issue is outside the scope of the present review.

Some substances that fall within scope of the PSA (such as nitrous oxide) may have been recognised as a substance of misuse for some time and other substances covered may have been first synthesised a long time ago but not misused until recently. NPS may capture recently synthesised substances that are already controlled under the MDA, such as mephedrone. The substances within scope of the PSA have changed over time as some NPS have subsequently been controlled under the MDA (such as third-generation synthetic cannabinoids[16]).

There have been 3 types of legal challenges to the PSA, concerning the medicinal products exemption for nitrous oxide, the psychoactivity of nitrous oxide and synthetic cannabinoids. In all these cases, the courts have ruled that the substances involved are indeed subject to the provisions of the Act. The cases relating to nitrous oxide have been taken to the Court of Appeal, and the judgements reflect binding decisions.[1]

There is no known evidence of exempted activities or the trade in exempted substances being adversely affected by the PSA, and the list of exemptions has not been amended since the Act was introduced.[1]

3 | ENFORCEMENT OF THE UK PSA

Data from police forces (supplied on a voluntary basis and only available for 44 of the 46 forces in the UK 6 months after the Act was introduced) suggest that the PSA has led to *head shops* either closing down or no longer selling NPS, with 332 retailers identified as having ceased the sale of new psychoactive substances. This has been achieved through more extensive use of the powers to arrest individuals and seize substances within the scope of the PSA, with 492 arrests and 989 seizures recorded by police forces. The most

seizures related to synthetic cannabinoids (358) followed by unspecified NPS powders (261) followed by nitrous oxide (202) and other NPS (such as tablets or capsules; 168).[1] The number of offences peaked soon after the PSA was introduced with 141 offences between July and September 2016 falling to 60–80 offences per quarter during 2017.[1] Most prosecutions appear to have been for intent to supply (69%).[1]

This suggests that the Act has not completely eliminated the supply of NPS, given the large numbers of offences and seizures of suspected NPS recorded. While the open retailing of NPS has ceased, it appears that NPS continue to be sold, albeit less visibly.[1]

4 | SUPPLY AND DEMAND AFTER INTRODUCTION OF THE UK PSA

The available evidence on price and availability, which is largely qualitative research due to a lack of systematic data, suggests that the PSA caused the prices of NPS to increase and their availability to fall. Street dealers seem to be becoming the main source of NPS, particularly for synthetic cannabinoids.[17] However, the Crime Survey for England and Wales data suggest that shops and the internet remain important sources of NPS for recreational users.

The large majority of online NPS vendors in the UK voluntarily removed NPS from their sites or closed down completely before the PSA was introduced. The National Crime Agency identified 104 websites operating to supply NPS in the UK prior to the introduction of the PSA. Following the introduction of the Act 38 sites were removed by their owners, 30 stated they were closed for business or removed any reference to NPS, 17 moved their operations to the EU and 7 with co.uk domains were suspended by the National Crime Agency.[1]

It does not appear that the PSA has significantly disrupted darknet sources for NPS activity[18] and it appears that the emergence of new NPS in the UK has not ceased following the introduction of the PSA. Large amounts of synthetic cannabinoids remained available via the darknet in 2016 and 2017.[1]

5 | PREVALENCE OF USE FOLLOWING INTRODUCTION OF THE UK PSA

There has been a considerable reduction in NPS use amongst the general adult population since the introduction of the PSA, mainly driven by a reduction in use among those aged 16 to 24 (Figures 1, 2 and 3).

There has been an increase in Class A drug use amongst 16–59-year-olds between 2016/17 and 2017/18, although it is not clear whether it is partly driven by the PSA, given that this increase occurred over a different time period and in different demographics to the fall in NPS use.[1] The increase was mainly driven by use of powder cocaine and MDMA with increased use of tranquillisers and ketamine also.[1] The use of other drugs covered by the MDA such as ketamine has also shown an increase over this time period (Figure 1).

There does not appear to have been a statistically significant change in the use of NPS among those aged under 16 years. Similarly, it appears that the use of nitrous oxide (among all adults) does not appear to have been affected by the Act, although there are limited time series data from which to draw comparisons.[1]

The prevalence of NPS among vulnerable users appears to be more mixed, with qualitative evidence suggesting a significant fall in NPS use in some regions, and other regions remaining unaffected by the Act. There is a range of qualitative evidence suggesting that there has been some displacement from NPS to *traditional* drugs for vulnerable users, although there is a lack of quantitative data on the magnitude of this displacement.[1]

In prisons, evidence from sources such as HM Chief Inspector of Prisons reports, random mandatory drug testing and the Scottish Prisoner Survey, indicates that the use of NPS (particularly synthetic cannabinoids) was widespread before the Act, and this has continued or in some cases increased since the Act was introduced.[1]

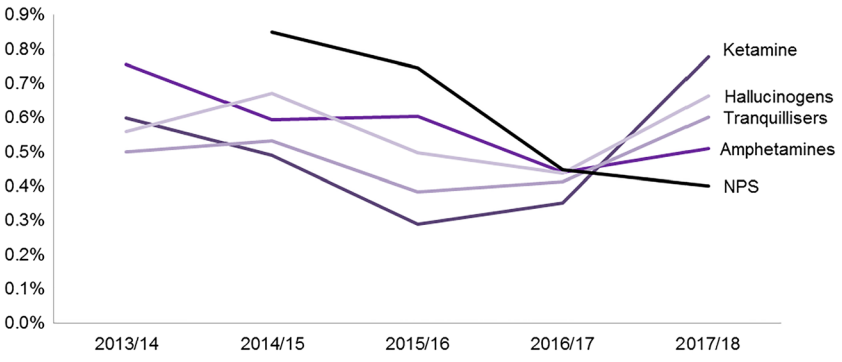

FIGURE 1 Use of novel psychoactive substances (NPS) and other selected drugs by 16–59-year-olds in England and Wales, 2013/14 to 2017/18. From https://www.gov.uk/government/publications/review-of-the-psychoactive-substances-act-2016[1] with permission. Data from crime survey for England and Wales. It is not possible to attribute the increases seen to a reduction in the use of NPS as the increase in the use of other drugs is seem across all age groups whereas the reduction in use of NPS is driven by changes in the younger age group (see Figure 3) and note differences in scale for Figures 2 and 3

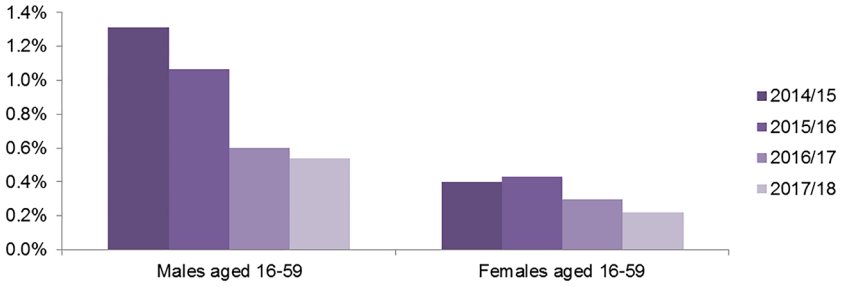

FIGURE 2 Prevalence of novel psychoactive substance use among 16–59-year-olds in England and Wales 2014/15 to 2017/18. From https://www.gov.uk/government/publications/review-of-the-psychoactive-substances-act-2016[1] with permission. Data are taken from the crime survey for England and Wales. The fall in prevalence may be due to unwillingness to admit taking NPS now they are subject to legal control. This seems unlikely as the fall in prevalence is driven by those reporting taking another illicit drug so is more likely to be due to be driven by reduced availability or increase in price[1]

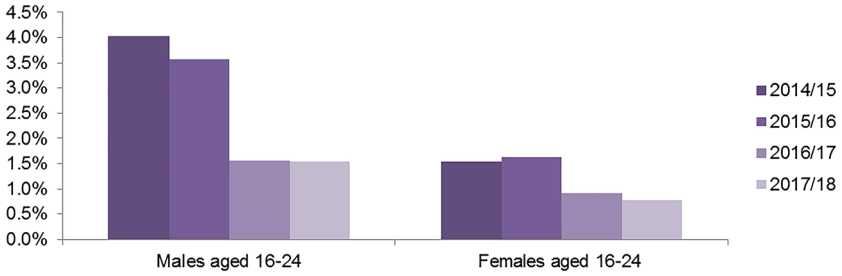

FIGURE 3 Prevalence of novel psychoactive substance use among 16–24-year-olds in England and Wales 2014/15 to 2017/18. From https://www.gov.uk/government/publications/review-of-the-psychoactive-substances-act-2016[1] with permission. Data are taken from the crime survey for England and Wales. The fall in prevalence in young males from 2.6% in 2015/2016 to 1.2% in 2017/2018 is statistically significant[1]

6 | HEALTH AND SOCIAL HARMS

Analysis of samples indicates that the potency of NPS, particularly of synthetic cannabinoids, has increased since the PSA was introduced, although this does seem to be an international trend.[1] The role of the PSA in this increase is not clear, given the wider global trend of increasing potency over this period.

The number of medical enquiries to the National Poisons Information Service related to NPS and the number of concerns reported by NPS users began to fall before the Act was introduced, and has continued to fall following its introduction. Data from the National Poisons Information Service should be treated with caution as there are numerous factors involved in determining whether enquiries are made and some instances of harm resulting from NPS may therefore go unrecorded.

However, some data suggest that there has been a fall in the proportion of patients with severe toxicity, who have analytically confirmed NPS exposure, since the PSA was introduced. Local evidence from Edinburgh and London shows a more mixed picture, with no significant falls in NPS-related admissions.[1] However, when hospital presentations and admissions due to NPS consumption were correlated with the introduction of Temporary Class Drug Orders for specific substances and the implementation of the PSA (with seizure of controlled substances from the point of sale) then there was a significant reduction in both presentations and admissions over a 12-month period.[19]

The number of individuals in treatment for NPS has generally fallen since the Act, particularly for NPS with a predominantly stimulant effect.[1] The trend in NPS-related deaths differs considerably by country, with a reduction in deaths in England and Wales contrasted by a significant increase in deaths in Scotland (but see Reuter and Pardo[21] for a more optimistic view of the Scottish situation).

The Act has not prevented the continued violence and health harms related to NPS use in secure settings, with serious incidents continuing to be reported across most adult male prisons in inspectorate reports. However, there is insufficient evidence to draw any conclusions on the impact of the Act on violence or crime outside of prison settings.[1]

7 | DISCUSSION AND CONCLUSIONS

It may be argued that an insufficient period of time has elapsed for a true estimate of the impact of the UK PSA to be reached and it may be helpful to consider the situation in countries where legislation has been in place for a longer period. The New Zealand Ministry of Health has recently published a report of the workings of their Act between 2013 and 2018.[20] The Act has not enabled the availability of low risk NPS through a regulated market as originally intended. They concluded that their market for NPS still exists but has been driven underground making statistics difficult to obtain. Coroner's reports suggest that 40–50 deaths attributable to NPS were under investigation at the time of the report. Although regulations are in place to allow registration of NPS shown to be safe prior to legal sale, no applications have been received for licenses for retailing, manufacture or wholesaling of such products. Licenses have been granted for research and for importation for the purposes of research. Convictions for supply have increased

markedly between 2013 and 2017 and the amount of seized material has also shown a large increase notably at the point of importation to NZ. They are now considering whether wider drug regulation reform is necessary.[20]

The Irish situation has also been recently assessed through a study of the National Drug Prevalence Survey and a study of the national database of drug-related psychiatric admissions. The Prevalence Survey data showed a marked reduction in the population use of NPS from 2010 to 2015.[7] Additionally there was a sharp decline in the presentation of clients with NPS-related substance use disorder over this time period. During the period 2008–2010 when *head shops* were most active up to the introduction of the Irish PSA in 2010, there was an increase in the monthly rate of drug-related psychiatric admissions. From mid-2010 to 2012 there was a downward trend in admissions being most marked in young males aged 18–24 years.[8] Whilst being cautious about causation the authors concluded that steps taken in Ireland to address NPS were associated with a positive public health benefit.

Most of the main aims of the UK PSA appear to have been achieved, with the open sale of NPS largely eliminated, a significant fall in NPS use in young people and the general population, and a reduction in health-related harms, which is likely to have been achieved through reduced usage. Criticism of the UK approach[21] may therefore have been premature.

However, some areas of concern have remained or emerged since the Act, such as the supply of NPS by street dealers, the continued development of new substances,[22] the potential displacement from NPS to other harmful substances, and continued high levels of synthetic cannabinoid use among the homeless and prison populations. Importantly there is little objective information on the true level of morbidity due to use of NPS following the introduction of the PSA and this needs continuous monitoring. The ongoing National Institute of Health Research NPS project[23] may provide pointers for how this situation is best managed in the future.

A variety of schemes for controlling and regulating the supply of NPS have been devised and trialled around Europe.[23] None of these appear to have been completely successful although it is important to remain mindful of international best practice.[1] It is hoped that a re-examination of the effectiveness of the PSA after it has been in place for a more substantial period of time will reveal a sustained benefit to those a risk due to use of NPS.[24]

COMPETING INTERESTS

Although R.G.H. was a member of the ACMD until early 2019 all of the views expressed in the talk or this review are the personal opinion of the author and should not be interpreted as being the official views of ACMD or of the Home Office. There are no conflicts of interest to note other than this.

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